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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,187	11/02/2000	Enoch Kim	11641/6	4852

26646 7590 07/25/2003

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EXAMINER

PENG, KUO LIANG

ART UNIT

PAPER NUMBER

1712

DATE MAILED: 07/25/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/705,187

Applicant(s)

KIM, ENOCH

Examiner

Kuo-Liang Peng

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/19/03 Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 53-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 53-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The Applicants' amendment filed on June 19, 2003 was received. Claim 1 is amended.

Claims 16-52 are deleted.

2. The indicated allowability of claims 2-15, 53-59 and 63-66 are withdrawn in view of new consideration and newly discovered references as described in this Office Action. Examiner apologies for any inconvenience.

3. Applicant is advised that should Claims 7 and 8 be found allowable, Claims 53 and 54, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1-4, 10-11, 14-15, 55, 60 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Reeves (US 5,961,479).

With respect to Claims 1, 60 and 62, Reeves discloses a hydrogel therapeutic mask having plurality of open surfaces of a predetermined size and spatially positioned (col. 1, line 64 to col. 2, line 13). The limitation of "stamp" and the preamble "polymer gel patterning element for patterning biological materials" are merely an intended use which does not carry any weight of patentability. See MPEP 2111.02. Note that the hydrogel therapeutic mask conforms a surface of a substrate upon contact with the surface.

With respect to Claims 2-4, 55 and 63-64, Reeves discloses a hydrogel therapeutic mask (i.e., reads on a polymer gel contact mask) having plurality of open surfaces of a predetermined size and spatially positioned (col. 1, line 64 to col. 2, line 13). The hydrogel can be made by polyacrylamide, poly-2-hydroxyethylmethacrylate(i.e., polyHEMA), etc. (col. 2, lines 52- 67). Note that the hydrogel therapeutic mask conforms a surface of a substrate upon contact with the surface.

With respect to Claims 10-11 and 14, as mentioned previously, Reeves discloses a hydrogel therapeutic mask (i.e., reads on a polymer gel contact mask) having plurality of open surfaces of a predetermined size and spatially positioned (col. 1, line 64 to col. 2, line 13).

With respect to Claim 14, the hydrogel can be made by polyacrylamide, poly-2-hydroxyethylmethacrylate(i.e., polyHEMA which is a polymethacrylate), etc. (col. 2, lines 52- 67).

With respect to Claim 15, as mentioned previously, Reeves discloses a hydrogel therapeutic mask (i.e., reads on a polymer gel contact mask). It is noted that Claim 15 is a

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product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Reeves’ hydrogel therapeutic mask is substantially similar to that of the Applicants polymer gel contact mask, Reeves’ disclosure reads on the limitation of the present claimed invention.

6. Claims 1-4, 6, 9-11, 14-15, 55-58, 60 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Wichterle (US 3 220 960).

With respect to Claims 1-4, 6, 9, 14, 55-58, 60 and 62-64, Wichterle discloses a hydrogel (col. 1, line 30) which can be prepared from ethylene glycol monomethacrylate, acrylamide and ethylene glycol dimethacrylate (Example V). The limitation of “stamp” and the preamble “polymer gel patterning element for patterning biological materials” are merely an intended use which does not carry any weight of patentability. See MPEP 2111.02. The hydrogel can be a contact lens or a semi-permeable membrane (col. 1, lines 27-45 and col. 4, line 8). The contact lens reads on a polymer gel contact mask because it contact with and masks on top of the eyes. Note that the contact lens conforms a surface of an eye upon contact with the surface.

With respect to Claims 10-11, the hydrogel can have a large number of parallel channels or conduits which are formed by fibers (col. 3, lines 20-34 and Example VIII).

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With respect to Claim 15, it is noted that the instant claim is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Wichterle’s contact lens is substantially similar to that of the Applicants polymer gel contact mask, Wichterle’s disclosure reads on the limitation of the present claimed invention.

7. Claims 1-4, 6-7, 9, 13, 15, 53, 55-57, 60 and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Atkinson (US 4 361 657).

With respect to Claims 1-4, 6-7, 9, 53, 55-57, 60 and 62-63, Atkinson discloses a hydrogel contact lens obtained by copolymerizing a HEMA, a crosslinking monomer and styrene or substituted styrene (col. 1, lines 43-66). . Note that styrene is considered as a hydrophobic monomer (col. 2, lines 32-46). The limitation of “stamp” and the preamble “polymer gel patterning element for patterning biological materials” are merely an intended use which does not carry any weight of patentability. See MPEP 2111.02. The contact lens which contacts with and masks on the eyes reads on Applicants’ contact mask. Note that the contact lens conforms a surface of an eye upon contact with the surface. The crosslinking agent can be a di(meth)acrylate in an amount of up to 5 wt% (col. 2, lines 15-31).

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With respect to Claim 13, the contact lens can have a thickness of 0.25 mm (col. 5, lines 18-30).

With respect to Claim 15, it is noted that the instant claim is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Atkinson’s contact lens is substantially similar to that of the Applicants polymer gel contact mask, Atkinson’s disclosure reads on the limitation of the present claimed invention.

8. Claims 1-4, 6, 8-9, 15, 54-57 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Ken (US 6 113 629).

With respect to Claims 1-4, 6, 8-9, 54-57 and 60, Ken discloses a polymer gel which can be heparin, heparin sulfate, polyethylene glycol, collagen-HEMA hydrogel, etc. (col. 3, lines 14-65). Note that collagen is biodegradable. The limitation of “stamp” and the preambles “polymer gel patterning element for patterning biological materials”, and “contact mask” are merely an intended use which does not carry any weight of patentability. See MPEP 2111.02. The polymer gel can be crosslinked by dimethacrylate (col. 3, lines 50-65).

With respect to Claim 15, it is noted that the instant claim is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process,

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determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Ken’s polymer gel is substantially similar to that of the Applicants polymer gel contact mask, Ken’s disclosure reads on the limitation of the present claimed invention.

9. Claims 2-3, 15, 55, 59 and 63-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Takezawa (US 2002/0086423).

With respect to Claims 2-3, 55, 59 and 63-66, Takezawa discloses a collagen hydrogel thin film on a polystyrene culture dish for culturing cells ([0033] and [0035]-[0038]).

With respect to Claim 15, it is noted that the instant claim is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Takezawa’s collagen hydrogel is substantially similar to that of the Applicants polymer gel contact mask, Takezawa’s disclosure reads on the limitation of the present claimed invention.

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10. Claims 1-7, 9, 15, 53, 55-57 and 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Powers (US 4 702 732).

With respect to Claims 1-7, 9, 53, 55-57 and 59-63, Powers discloses a polymer matrix 10a or 20b which is in conformal contact with a conductive member 10a or 10b, respectively (col. 11, lines 4-24). Note that the conductive member is an inanimate substrate. The polymer matrix can be HEMA homopolymer or HEMA copolymer using di(meth)acrylate as a crosslinker (col. 16, line 66 to col. 17, line 18 and col. 18, lines 29-46). A hydrophobic monomer such as methyl methacrylate can be used as a comonomer for preparing the polymer matrix (col. 18, lines 23-28). The hydrogel can transdermal delivery of pharmacologically active ligands (col. 17, lines 57-68). In other words, this polymer matrix functions as a polymer gel patterning element for patterning biological materials. Furthermore, the limitation of “stamp” and the preamble “contact mask” is merely an intended use which does not carry any weight of patentability. See MPEP 2111.02.

With respect to Claim 15, it is noted that the instant claim is a product-by-process claim. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Since Powers’ polymer matrix is substantially similar to that of the Applicants polymer gel contact mask, Powers’ disclosure reads on the limitation of the present claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves.

Reeves discloses a hydrogel therapeutic mask as described in paragraph 5, which is incorporated herein by reference. It is noted that the size of the holes and the thickness of the mask are result-effective variables because the size of the holes must conform the size of eyes, etc. and the thickness must be provide proper strength of the mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention through routine experimentation to whatever hole size or mask thickness in order to afford a proper therapeutic mask.

13. Claims 5-6, 9 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves in view of Wichterle (US 3,220,960).

Reeves discloses a hydrogel therapeutic mask as described in paragraph 5, which is incorporated herein by reference.

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With respect to Claim 5-6 and 56, the difference between Reeves and the present invention is the requirement of the use of a crosslinking agent that can be diacrylate or polyacrylate.

Reeves teaches the desire of the use of a hydrogel therapeutic mask which is self-sustaining (i.e., strong in physical properties) (col. 1, lines 52-55). Furthermore, it is well known that polyHEMA is usually obtained by polymerizing HEMA with a crosslinking agent. For example, Wichterle discloses a hydrogel obtained by polymerizing of a mixture comprising ethylene glycol monomethacrylate (i.e., HEMA) and ethylene glycol dimethacrylate as a crosslinking agent (Example V). The amount of the crosslinking agent can be 1 % (col. 2, lines 17-19)(i.e., 0.6 mole % (MW of HEMA is 130 and MW of ethylene glycol dimethacrylate is 198) which reads on about 1 mole %). The motivation of using the crosslinking agent is to impart the elasticity to the resulting hydrogel (Example V). In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize the ethylene glycol dimethacrylate as a crosslinking agent in Reeves composition with expected success, and thereby obtained the present invention.

With respect to Claim 9, Wichterle further teaches the use of the crosslinking agent in an amount of 1 % (col. 2, lines 17-19)(i.e., 0.6 mole % which reads on about 1 mole %)(Note: molecular weight of HEMA is 130 and that of ethylene glycol dimethacrylate is 198).

14. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wichterle.

Wichterle discloses a semi-permeable hydrogel as described in paragraph 6, which is incorporated herein by reference. It is noted that the size of the holes and the thickness of the

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mask are result-effective variables because the size of the holes and the thickness of the semi-permeable hydrogel must be adequate in order to allow certain material pass through while retain other materials. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention through routine experimentation to whatever hole size or thickness in order to afford a proper semi-permeable hydrogel.

Response to Arguments

15. Applicant's arguments with respect to Claims 1-15 and 53-66 have been considered but are moot in view of the new ground(s) of rejection.

The rejection of the instant claims is described above.

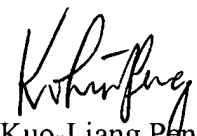
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

klp
July 22, 2003


Kuo-Liang Peng
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